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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,140	03/25/2004	Hassan Chaouk	BioCure 260	7389
44260	7590	09/09/2005	EXAMINER	
LAW OFFICE OF COLLEN A. BEARD, LLC P. O. BOX 1064 DECATUR, GA 30031-1064			DANIELS, MATTHEW J	
			ART UNIT	PAPER NUMBER
			1732	
DATE MAILED: 09/09/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/809,140

Applicant(s)

CHAOUK ET AL.

Examiner

Matthew J. Daniels

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. The arguments presented traversing the election requirement, in the reply filed on 22 August 2005, do not appear to affirm the election made in this case. However, the arguments directed to Claims 9-12 will be interpreted to be affirmation of the election. The traversal is on the ground(s) that Claims 9-12 claim a product that cannot be made by a different method since they are clearly drawn to products made by a specific method. This is not found persuasive because articles or products are defined by structural and compositional limitations, and not by the methods used to form the article or product. Because the same structure could be produced by a different method (namely stereolithography, as cited in the previous action), and because the arguments presented do not provide any reasons as to why this method could not produce the same product, the Examiner finds the arguments not to be persuasive. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (USPN 6152943) in view of Tanabe (USPN 5443454). **As to Claim 1**, Sawhney teaches a method for forming a hydrogel comprising the steps: providing a delivery device having a gelation chamber (Fig. 3); providing a prepolymer composition that will form a hydrogel when brought into contact with a gelation initiator (2:64-3:6); contacting the prepolymer with the gelation initiator in the gelation chamber so that it forms a hydrogel in the gelation chamber (10:1-24); and extruding the hydrogel from the delivery device (Fig. 5A and 10:15-17). Sawhney appears to be silent to forming or extruding a string. However, this aspect of the invention would have been obvious over Tanabe, who teaches liquid substances introduced through lumen into a mixing chamber (Fig. 8A, Item 40c) and reactively solidifying to form a solid line or filament (13:44-54). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the method of Tanabe with that of Sawhney in order to eliminate the dispersing and leakage of an embolic material out of the site of an aneurysm (Tanabe, 4:48-59). **As to Claim 2**, both Sawhney (Figs. 3 and 4) and Tanabe (Fig. 8A) teach a catheter delivery device. **As to Claim 3**, both Sawhney (Fig. 3, Items 49 and 49') and Tanabe (Figs. 8A, 8B, 9A) teach a multilumen catheter. **As to Claim 4**, both Sawhney (Fig.

3, Item 46) and Tanabe (Fig. 8A, Item 40c) teach a gelation chamber. **As to Claim 5**, Tanabe teaches a catheter that is coaxial having an inner catheter and an outer catheter and the method further comprising the step of sliding the inner catheter within the outer catheter to increase or decrease the length of the gelation chamber (14:16-18). **As to Claim 6**, Sawhney teaches a method wherein the prepolymer composition comprises at least two solutions that will form a hydrogel when combined in the gelation chamber (7:1-14 and 10:1-24). **As to Claim 7**, it would have been obvious or inherent in the method of Sawhney that hydrogel would have been extruded as prepolymer composition was moved to the gelation chamber (10:1-24). **As to Claim 8**, Sawhney teaches a hydrogel being formed in the gelation chamber, but is silent to the other claimed limitations. However, Tanabe teaches a delivery device that is a coaxial dual lumen catheter and the inner catheter is slidable within the outer catheter so that the degree of polymerization can be altered as the inner catheter is slid towards the distal end of the gelation chamber (14:16-18).

Response to Arguments

4. Applicant's arguments filed 22 August 2005 have been fully considered but they are not persuasive. The arguments appear to be on the following grounds:

- a) Sawhney teaches a method without premature crosslinking – in other words, without crosslinking the liquids until they are in the cavity or void (Page 4).
- b) Sawhney nowhere suggests that the hydrogel is formed within the mixing chamber or that a solid, formed hydrogel is extruded from the catheter. (Page 4)

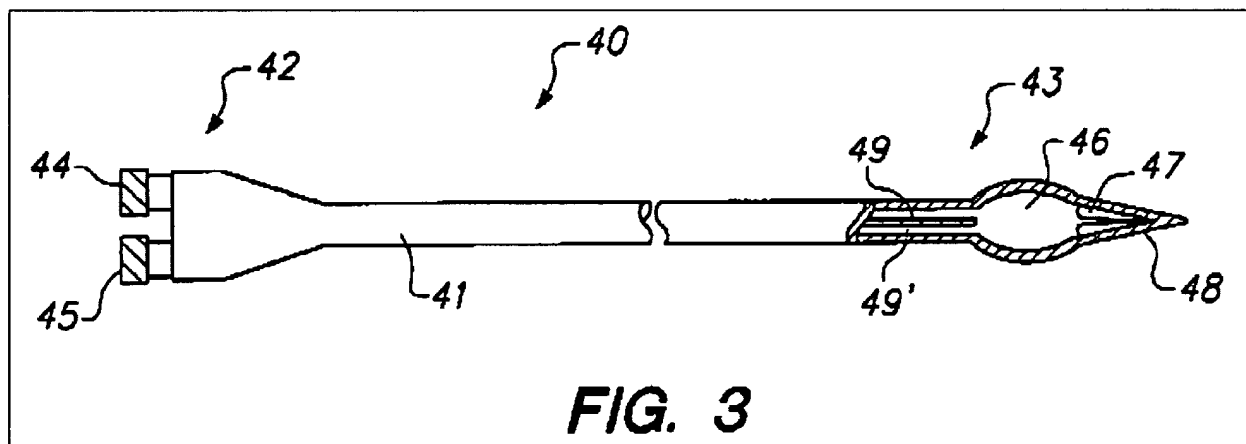
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c) Sawhney teaches away from delivering a hydrogel string, and the Abstract states that the delivery system is configured to deliver two or more prepolymer solutions without premature crosslinking. The hydrogel string of the claimed invention is certainly the result of the “premature crosslinking” that Sawhney teaches to avoid. (Page 5)

d) One would not be motivated to make the combination since Sawhney already teaches a solution (Page 5)

5. These arguments are not persuasive for the following reasons:

a-c) The Examiner respectfully disagrees with the assessment of Sawhney’s method presented in the arguments. In particular, the Examiner cites the following portion of Sawhney’s method (Fig. 3 and 10:1-25):



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Delivery system 40 is particularly suitable for use where the polymeric material is to be applied to a surface of a natural or induced body lumen or void, and through which a body fluid is not flowing at very high velocity. Prepolymer solutions are injected via lumens 49 and 49' into mixing chamber at a rate selected so that the prepolymer solutions begin crosslinking in chamber 46, with the resulting partially-formed gel being extruded through outlet ports 47 into the lumen or void. In this manner, washout or dilution of the prepolymer solutions during deposition is reduced or eliminated, thereby reducing the risk that the prepolymer solutions will cause embolization in other portions of, for example, the vascular system.

Delivery system 40 therefore prevents premature crosslinking of the prepolymer solutions, while also enabling the solutions to be mixed and partially gelled before being deposited in the body lumen or void. Delivery system may be especially useful in depositing hydrogel systems that form both physical and chemical crosslinks, wherein the physical crosslinking is accomplished by mixing the prepolymer solutions in mixing chamber 46. The partial gel extruded from mixing chamber 46 through outlet ports 47 then may have sufficient mechanical integrity to remain in position in the body lumen or void during the chemical crosslinking process.

The arguments to Sawhney's alleged teaching away from the instant invention are acknowledged. However, it is the Examiner's position that this is not what Sawhney teaches. Sawhney specifically teaches that the solutions "...begin crosslinking in chamber 46, with the resulting partially-formed gel being extruded...into the lumen or void." (10:7-9, emphasis added) Sawhney's specific teaching of a partially-formed gel appears to contradict the arguments presented. Additionally, Sawhney particularly teaches that one desires to avoid washout or dilution (10:8-12), and thus it would have been obvious or inherent that the extrudate would have existed in a state sufficiently formed (See "formed" in 10:8) that it would not have been dispersed or swelled (diluted) by the vascular liquid. Sawhney's partially formed gel would have therefore obviously or inherently existed with some string-like characteristics. Additionally, the

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Examiner cites Merriam-Webster's Collegiate Dictionary, tenth edition (Page 414) for teaching that one definition of "extrude" is "to shape by forcing through a die" (emphasis added, Page 414, left column, top). In view of the portions of Sawhney's method cited, the claim is still deemed to be prima facie obvious when combined with Tanabe, who teaches that extrusion of strings of other materials is known (Columns 14-15).

d) The arguments presented appear to indicate that there is no motivation to make the combination because Sawhney teaches away from such a combination. However, Tanabe also teaches the two components that "...react and begin to solidify" (14:12-13). Moreover, the rejection of Claim 1 reads that "It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the method of Tanabe with that of Sawhney in order to eliminate the dispersing and leakage of an embolic material out of the site of an aneurysm (Tanabe, 4:48-59)." Sawhney teaches that washout and dilution can be a problem (10:10-12) and Tanabe teaches a method which specifically seeks to resolve the problems of leakage of embolic material (4:50-52). The Examiner submits that the motivation provided is valid.

Tanabe also teaches that the length of the chamber can be adjusted (14:15-18). One of ordinary skill would have understood that complete gelling in Sawhney's chamber could have led to clogging of the chamber (Note in particular the size of the orifices in Fig. 3 compared to the diameter of the mixing chamber, Item 46). However, no clogging appears to be present in Tanabe's method, and thus there appears to be additional motivation to incorporate the method in order to improve upon Sawhney's method by providing a device having less susceptibility to clogging.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Daniels whose telephone number is (571) 272-2450. The examiner can normally be reached on Monday - Thursday, 7:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJD 9/1/05



MICHAEL P. COLAIANNI
SUPERVISORY PATENT EXAMINER